

REMARKS

Applicants appreciate the opportunity provided by the Examiner to present this response. Claims 1-19 are pending. Claims 1, 11 and 12 are currently amended. Claim 6 is cancelled. Claims 9 and 10 have been cancelled previously. Claims 17-19 are withdrawn. Support for the amendments is found, for example, from paragraph [0042], page 16 to paragraph [0045], page 17 of the specification. No new matter is introduced. Accordingly, entry and consideration of this response is respectfully requested.

In the Office Action dated May 25, 2006, the Examiner has objected to the drawings of the application under 37 C.F.R. §1.83 (a) as failing to show every feature of the invention specified in the claims. Particularly, the Examiner has alleged that the reflector in claim 6 and the ultrasonic transducer element in combination with the compliant member for varying distance must be shown in the drawings. Applicants have cancelled claim 6 and the feature of the ultrasonic transducer element from the claims, thus rendering the objection overcome. Moreover, the cancellation of claim 6 renders any rejection thereof moot.

In the Office Action dated May 25, 2006, the Examiner has rejected claims 11-16 under 35 U.S.C. §112, 1st paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner has alleged that the specification does not describe an applicator including an ultrasonic transducer, a compliant material, and an electrode located on the surface of the compliant material in such sufficient detail to allow one skilled in the art to make and/or use the invention. Applicants have amended claim 11 to delete the feature of the ultrasonic transducer and instead recite the feature of “means for conducting energy to a surface of the tissue”.

Thus, the rejection of claims 11-16 under 35 U.S.C. §112, 1st paragraph, is overcome and withdrawal thereof is respectfully requested. Moreover, Applicants respectfully

maintain that the “means for conducting energy to a surface of the tissue” is directed to electrodes and equivalents thereof, and the means can be operatively connected to other conventional energy sources, such as ultrasound, microwave, cryoablation, radio-frequency(RF), photodynamic, laser or cautery.

In the Office Action dated May 25, 2006, the Examiner has rejected claims 1, 2, 4-6 and 11-14 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent Publication No. 2002/0042610 to Sliwa, Jr. et al. (hereafter “Sliwa”). The rejection is respectfully traversed.

To maintain a rejection of a claim under 35 U.S.C. §102(b), a reference must teach each and every element of the claimed invention. Sliwa does not do so.

Applicants’ independent claim 1, as amended, recites an applicator for creating a lesion in tissue. The applicator comprises, *inter alia*, a first rigid or semi-rigid support member, a first compliant material coupled to the first support member, a first passage in communication with the first compliant material for infusing a medium into the compliant material to inflate the compliant material, and at least one electrode for conducting energy to a surface of the tissue. Significantly, the electrode contacts the tissue surface directly and the inflation of the compliant material secures the contact between the electrode and the tissue surface.

Applicants’ independent claim 11, as amended, recites an applicator for creating lesions in tissue. The applicator comprises, *inter alia*, a first rigid or semi-rigid support member, means for conducting energy to a surface of the tissue mounted to the first support member, and means for varying the distance between the means for conducting energy to the surface of the tissue and the surface. Significantly, the energy conducting means contacts the tissue surface directly, and the means for varying the distance between the energy conducting means and the tissue surface secures the contact between the energy conducting means and the tissue surface.

Sliwa discloses an ablation device 400 (Figure 67) comprising a number of adjacent cells 402, each having an ultrasonic transducer 406 housed within a housing 410 comprised of an enclosure 412 and a top 414. The housing 410 is then mounted into an opening 446 in a suction body 448 that is further provided with suction recesses 454 (Figure 64) for adhering the device 400 to tissue (paragraph [0209]). Sliwa further discloses a compliant membrane 460 filled with substance 458 or a solid element 459. The membrane 460 is adhered to the device 400 around the bottom of the enclosure 412 and between the transducer 406 and the surface 405 of body tissue. The membrane 460 may be made flexible and compliant to conform to the tissue. Particularly, the membrane 460 can be inflated or deflated during or between the activation of the transducer 406 to move the focus of the transducer relative to the tissue. However, nowhere does Sliwa teach or suggest at least one electrode or means for conducting energy to a surface of tissue, which electrode or energy conducting means contacts the surface directly. Further, Sliwa fails to teach the feature of a compliant material, the inflation of which secures the contact between the electrode and the surface. Sliwa also fails to show the means for varying the distance between the energy conducting means and the tissue surface, as presently claimed.

Therefore, Sliwa fails to teach each and every element of claim 1, from which claims 2 and 4-6 depend. Sliwa also fails to teach each and every element of claim 11, from which claims 12 and 14 depend. Thus, the rejection of claims 1, 2, 4-6 and 11-14 under 35 U.S.C. 102(b) is overcome and withdrawal thereof is respectfully requested.

In the Office Action dated May 25, 2006, the Examiner has rejected claims 1-3, 6-8 and 11-16 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,547,788 to Maguire, et al. (hereafter “Maguire”). The rejection is respectfully traversed.

To maintain a rejection of a claim under 35 U.S.C. §102, a reference must teach each and every element of the claims. Maguire does not do so.

Applicants' independent claims 1 and 11, as amended, are discussed above.

Maguire discloses a tissue ablation apparatus 100 for ablating a substantial portion of a circumferential region of tissue. The apparatus comprises a delivery member 102, an ablation member 128 comprised of an expandable member 108 and an ablation element 120 therein, and an ablation control system 118. Once the ablation apparatus 100 is inserted into a desired circumferential organ, tissue or vessel, fluid is introduced to the expandable member 108 to inflate the expandable member 108 and thus anchor the ablation member 128 in a desired position. Subsequently, the ablation element 120 is activated to ablate the targeted tissue and form the desired lesion within the organ, tissue or vessel (col. 22, lines 1-22). Thus, the expandable member 108, a balloon for example, is employed for the purpose of positioning and anchoring the ablation apparatus 100, but not for the purpose of securing the contact between the energy conducting member and the tissue surface.

Therefore, Maguire fails to disclose the feature of at least one electrode or means for conducting energy to a surface of tissue, which contacts the surface directly. Further, Maguire fails to teach the feature of a compliant material, the inflation of which secures the contact between the electrode and the surface, or the feature of means for varying the distance between energy conducting means, conducting energy to a tissue surface, and the surface, which feature secures the contact between the energy conducting means and the tissue surface. Thus, Maguire fails to disclose each and every element of claim 1, from which claims 2-3 and 7-8 depend. Maguire also fails to teach each and every element of claim 11, from which claims 12-16 depend. Accordingly, the rejection of claims 1-3, 6-8 and 11-16 under 35 U.S.C. 102(e) based on Maguire is overcome and withdrawal thereof is respectfully requested.

Thus, in view of the foregoing amendments and remarks, it is firmly believed that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. S. DiGiglio', written over the typed name.

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